

REMARKS/ARGUMENTS

The applicant's attorneys appreciate the Examiner's thorough search and remarks.

Responsive to paragraph 2 of the Office Action, the references cited by the Examiner have been resubmitted for consideration.

Responsive to paragraphs 4 and 5 of the Office Action, claims 12 and 13 have been amended to clarify the recitations thereof. Reconsideration is requested.

Claims 10, 12-15, 17, 19 and 21 have been rejected under 35 U.S.C. §102(b) as anticipated by Perouse et al. (Perouse), U.S. Patent No. 5,346,115. Reconsideration is requested.

Claim 10 has been amended to call for the following combination:

10. A stapler for laparoscopic aortic repair by intraluminal fixation of an intravascular device, including a graft or a stent-graft, to a blood vessel, comprising:

a tubular body configured for positioning within the blood vessel, said tubular body being rigid in longitudinal direction and flexible in lateral direction, the tubular body carrying,

a substantially cylindrical head disposed at one end of the tubular body, the cylindrical head having an inner cavity, a proximal end and a distal end; the cylindrical head being connected to a die loadable with fastener means, including U-shaped staples, the die being configured as a barrel having a proximal end, a distal end, a substantially cylindrical peripheral surface and an inner cavity open at the distal end, said barrel having radial slots opening at the peripheral surface, and said die having recesses at the proximal end thereof provided with grooves for receiving the fastener means while each of said grooves being configured with a couple of curvilinear guiding faces located adjacent to the peripheral surface of the die and diverging towards the peripheral surface of the die such that free ends of said fastener means are bent when the fastener means are displaced along the grooves towards peripheral surface of the die; the die being closed by

a die lid having a through axial hole, a substantially cylindrical peripheral surface, a proximal and distal end face, a plurality of radial slots extending onto said cylindrical surface, as well as a means for retaining the free ends of the fastener means in the grooves and means for separating the fastener means from the stapler at the end of a working stroke, said stapler further comprising,

a control mechanism disposed at a second end of the tubular body opposite to said head, said mechanism comprising a

cylindrical hollow body delimited by a proximal end and a distal end, said hollow body being connected to a retaining handle extending from the distal end sidewise at an angle from about 30 degrees to about 90 degrees, and said control mechanism further comprising,

a control lever pivotally mounted on said retaining handle and a pressure rod located within said hollow body, having a longitudinal axis, a proximal end and a distal end, the pressure rod being rigid in longitudinal direction and flexible in lateral direction and being operatively associated via its distal end with said control lever and its proximal end being located in the inner axial cavity of said die to allow for reciprocating therealong, said control mechanism further comprising a plurality of pivotable levers, deployed within the axial cavity of the cylindrical head that pivot upon application of axial force by the pressure rod, pivoting of said pivotable levers resulting in application of a radial force to a fastener means causing its radial displacement along the grooves; said stapler further comprising means for temporary fixation on the stapler body of intravascular devices, when it is put over the stapler body,

said means for temporary fixation comprising an adjusting screw to displace the pressure rod to such an extent that the free ends of the fastener means punch the wall of said intravascular device and prick the intravascular device.

A stapler according to claim 10 is distinguishable from the device shown by Perouse in the way it ejects the fastener means (e.g. a U-shaped staple) from the die toward an intravascular device (e.g. a graft or a stent graft) and in the way the fastener means is secured to the intravascular device and the blood vessel.

In Perouse, a fastener means is ejected by hammers 98 driven linearly in the radial direction by a rotating disc 86 having spiral channels 106 arranged symmetrically on opposite faces of the disc. Disc 86 rotates upon the rotation of driving nut 39 and thus spiral channels 106 interact with respective drive projections 108 disposed on respective faces of hammers 98 and displace the hammers. See columns 4, 5 and Figures 4-8 of Perouse.

On the other hand, a stapler according to the present invention ejects a fastener means by pivoting pivotable levers (e.g. levers 90, 92), driven by a pressure rod (e.g. rod 24). Thus, claim 10 calls for "a plurality of pivotable levers, deployed within the axial cavity of the cylindrical head that pivot upon application of axial force by the pressure rod, pivoting of said pivotable

levers resulting in application of a radial force to a fastener means causing its radial displacement along the grooves", which are not shown or suggested by Perouse.

In addition, in Perouse, the fastener means are secured using an anvil that is disposed around the blood vessel. That is, when the fastener means are ejected they co-operate with the anvil. Thus, the anvil is an essential part of the device shown by Perouse. This is explicitly stated in column 1 of Perouse: "One of the two parts of the stapler inserter includes a stapler holder which contains a series of staples disposed in at least one ring with their points oriented radially, and means for ejecting these staples. The other part of the stapler inserter includes an anvil". In column 6, Perouse further states that "Anvil 40 has cavities 130 of known shape, intended to fold the points of staples 94 during stapling". In other words, the staples are not deformed when escaping the stapler during ejection. Rather, the staples are deformed after ejection, and upon meeting the anvil.

On the other hand, a stapler according to the present invention employs a principle for securing the staples that does not require an anvil. Specifically, a stapler according to the present invention bends the free ends of staples during ejection of the staples towards the blood vessel. To realize the deformation of staples upon ejection the grooves accommodating the staples are configured with bulges (e.g. bulges 48). The bulges may be, for example, V-shape due to having curvilinear diverging guiding faces (e.g. faces 50). Once the staples are ejected by the levers they are forcibly displaced along the grooves and their free ends become deformed by the guiding faces. Thus, claim 10 calls for "said grooves being configured with a couple of curvilinear guiding faces located adjacent to the peripheral surface of the die and diverging towards the peripheral surface of the die such that free ends of said fastener means are bent when the fastener means are displaced along the grooves towards peripheral surface of the die" which are not shown or suggested by Perouse.

Furthermore, it has been alleged that Perouse discloses "...a substantially cylindrical head (225).... a die (40)...". The elements 225 and 40, however, do not refer to a cylindrical head, but refer to an anvil, which as mentioned, is not recited in claim 10.

Moreover, the allegation that "a die (40) and die lid (82,207) being rigidly mounted at the proximal end of this head..." would not be correct in that element 40 is an anvil (and not a die) and is a separate element that cannot be rigidly connected to the head.

In addition, it would be a misinterpretation of Perouse to state that Perouse shows "a substantially V-shaped means (collar piece 112) for setting apart the ends of said U-shaped staples". The collar piece 112 (similarly to flange 82) is used as a flange for support of various elements of the staple holder 32A. It is not designed for and is not capable of setting apart the staples.

For the foregoing reasons, it is respectfully submitted that Perouse fails to anticipate claim 10. Reconsideration is requested.

Regarding the rejection of claims 12 and 13, it is respectfully submitted that Perouse's staple holder does not show any means for setting apart the ends of the fasteners. Thus, Perouse fails to anticipate claims 12 and 13. Reconsideration is requested.

Regarding the rejection of claim 14, it is respectfully submitted that element 100 is a recess for guiding the staples, while element 134 is not intended for accommodating the staples. Element 134 is a radial guide hole that is intended for guiding hammers 113 and not for accommodating staples. Thus, Perouse fails to anticipate claim 14. Reconsideration is requested.

Regarding the rejection of claims 15, 17, and 19, it is respectfully submitted that since element 40 is an anvil and not a die, the grooves 102 serve for guiding hammers and not the staples. Furthermore, in Perouse's staple holder, there is no means capable of setting apart the ends of the fasteners as in the present stapler. Thus, Perouse fails to anticipate claims 15, 17, and 19. Reconsideration is requested.

Regarding the rejection of claim 21, Perouse does not appear to explicitly mention that rod 205 is rigid in the longitudinal direction and flexible in the lateral direction. Indeed, it appears that the rod of Perouse should not be rigid in the longitudinal direction due to the annular channels 226, 227 made at a rear or proximal end of the rod and spaced a small distance from each other. Thus, Perouse fails to anticipate claim 21. Reconsideration is requested.

Regarding the rejection of claim 18, it should be noted that the retention of the fasteners during their ejection from the die is important since it ensures more reliable guiding of the fasteners along the grooves. It is respectfully submitted, however, that there is no evidence in the record supporting the allegation that providing a torsion spring element to retain staplers would have been obvious to one skilled in the art. It is respectfully submitted that it would not be

obvious to modify the Perouse die and die lid to include the spring element. The retaining spring elements in a stapler according to the present invention are formed by virtue of cutting in the die lid 16 of weakening slots 42. The remaining zones of the die lid between the adjacent cuts constitute cantilever springy members 58. The element 82 of Perouse which has been erroneously identified as a die lid, in fact is one of the flanges 82, 84 between which disc 86 rotates, which in its turn guides the hammers. In other words, the element identified as corresponding to a die lid is not associated with fasteners. Therefore, it would serve no purpose to modify the die lid of Perouse to provide it with the ability to retain fasteners. Thus, claim 18 should not be deemed obvious over Perouse. Reconsideration is requested.

Regarding the rejection of claims 22 and 23, it should be noted that these claims depend from claim 10 and, therefore, should be deemed patentable for the reasons set forth above. Reconsideration is requested.

Claim 11 and claim 27 have been rejected as obvious over the combination of Perouse and Huxel, U.S. Patent No. 6,503,259. Reconsideration is requested.

It is respectfully submitted that for a skilled person who is familiar with the surgery of the vascular system it would not be obvious to combine Perouse and Huxel. Perouse discloses a device suitable for intravascular surgery, while Huxel discloses a device suitable for anastomotic surgery. During intravascular surgery a prosthesis is used for the repair of the same vessel. This is carried out by putting the prosthesis (graft or stent graft) inside a vessel and then by affixing its first end to one half of the vessel and its second end to another half of the same vessel. During anastomotic surgery a prosthesis (anastomotic device) is put outside of a vessel and then one end of the prosthesis is affixed to an end of the vessel, while the opposite end of the prosthesis is affixed to an end of the same or another vessel usually having a different diameter. Therefore, it would not be obvious to employ an adjusting screw of anastomotic device of Huxel in the intravascular staple inserter of Perouse. Furthermore, claim 11 and claim 27 depend from claim 10 and should be deemed patentable for the reasons set forth above. Reconsideration is requested.

Claims 16 and 24-26 have been rejected as obvious over the combination of Perouse with Dakov, U.S. Patent No. 5,720,755. Reconsideration is requested.

It is respectfully submitted that Figs. 14A and 14B of Dakov do not show V-shaped grooves with lateral guiding faces. Figs. 14A and 14B merely show an alternative embodiment for the driving elements, which urge the fasteners to eject. These elements are configured as actuators 414, which have a curvilinear shape. The actuators merely displace the fasteners without deflecting them. The fasteners become deflected due to the same principle, which is employed in Perouse , i.e. due to interaction with an outside anvil situated around the vessel. The alleged combination of Perouse and Dakov is irrelevant to claim 16, since neither Perouse, nor Dakov discloses grooves provided with curvilinear guiding surfaces for deflecting the fasteners when they are displaced along the grooves. Moreover, claims 16 and 24-26 depend from claim 10 and should be deemed patentable for the reasons outlined above. Reconsideration is requested.

Claim 20 has been rejected as obvious over the combination of Perouse and Irion, U.S. Patent Publication No. 2002/0007110. Reconsideration is requested.

Irion discloses an endoscope. Endoscopes are not in the same field as vascular surgery, and, thus could not be related to intravascular staples. Therefore, Perouse and Irion cannot be combined. In addition, even if the working head of the endoscope of Irion is considered to be the die of a stapler according to the present invention, the combination would not render claim 20 obvious because the working head is not made of a transparent material. The only transparent item mentioned in Irion is a trocar tube 1, which is not a part of the endoscope at all and which would not allow one to see the condition of the working head. Thus, claim 20 should not be deemed obvious over the combination of Perouse and Irion. Furthermore, claim 20 depends from claim 10 and, therefore, should be deemed patentable for the reasons set forth above. Reconsideration is requested.

In view of the amendments and the foregoing discussion, it is respectfully submitted that the application is in condition for allowance. Such action is earnestly solicited.

Respectfully submitted,

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